UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION,
PESTICIDES AND
TOXIC
SUBSTANCES

MEMORANDUM

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SUBJECT: Current EFED RED chapter for **Oxydemeton methyl**
(Case # 0258; Chemical # 058702; DP Bar code D259301)

DATE: Sept. 10, 1999

The purpose of this communication is to provide a copy of the current EFED RED chapter for Oxydemeton methyl (ODM). A copy of the RED chapter is attached.

It is our understanding that the most recent version in the ODM docket was dated Sept. 11, 1997. The version we are providing is updated to address comments we have received via the ODM docket. The RED chapter has been revised with regard to some points related to avian reproductive toxicity and effects on pollinators.

Estimated Environmental Concentrations (EECs) for ODM in Water Resources

The EECs for ODM in surface water in the updated RED chapter are based on a revision in July 1999, to make use of current model versions and correct assumptions regarding application rates. Previous EECs were based on PRZM 2.3 for simulating the agricultural field and EXAMS 2.94 for fate and transport in surface water. For the current RED chapter the EECs are based on the more recent model versions PRZM 3.12 and EXAMS 2.975. The revised EECs are displayed in Table 3 of the updated RED chapter. Risk quotients representing risk to aquatic organisms have been recalculated based on current aquatic EECs.

For Florida citrus, EFED has corrected the assumed application rates. The Florida citrus EECs were very different because the application rate assumed previously (1.88 lbs ai/A at 2 applications per year) is high relative to the correct application rate (0.375 lb ai/A at 2 applications per year). For all other scenarios the current EECs are similar to previous EECs. Results with two model versions are compared in an Appendix to the RED chapter.

For the ground water assessment, EFED has moved the comparative leaching assessment based on the PATRIOT model to an appendix.

Status of Data Requirements for ODM

Our memo on Sept. 11, 1997 discussed several data requirements primarily related to ODM metabolites. At this time, the position of EFED is not to request additional data for ODM or ODM metabolites to support the current labeled uses. If requests are submitted to reinstate additional uses, EFED would reevaluate this position. In particular, in case of a request to reinstate uses on major field crops such as corn, EFED would request more extensive data in order to characterize more completely the environmental fate and effects of ODM.

A relatively complete characterization of the environmental fate and effects of ODM would require studies of aerobic aquatic metabolism (162-4), leaching-adsorption-desorption (163-1), and terrestrial field dissipation (164-1) studies for ODM metabolites of concern. For ODM, the metabolites of concern are ODM-Thiol and 2-(ethylsulfonyl)ethane sulfonic acid (ODM ESOES). These metabolites were persistent in aerobic soil metabolism studies.

A relatively complete effects characterization would require testing of estuarine/marine fish and invertebrates (using technical grade active ingredient) because residues are expected to reach the marine/estuarine environment. EFED would reserve chronic testing for estuarine/marine fish and invertebrates pending results of the acute testing.

EFED would reserve toxicity testing for ODM metabolites pending a better understanding of the potential for aquatic exposure, based on the results of fate studies of the metabolites.

Contents of Section C

1. Use Characterization

Oxydemeton-methyl (ODM) is a systemic organophosphate insecticide primarily registered to control sucking and biting insects in agricultural crops. Approximately 45% of the ODM used in the U.S. (applied a.i.) is used on Cole crops, 20% on alfalfa grown for seed, and 15% on cotton (Gowan, 1997). Most of the use on Cole crops is on broccoli in the California Coastal and Central Valleys. Most of the use on alfalfa seed occurs in Idaho with the remainder being used in California. Most of the ODM used on cotton occurs in the Central Valley of California with a small amount being used in Texas. ODM is also used on numerous minor crops including strawberries, Christmas trees, eggplants, sugar beets, sweet corn, peppers, and watermelons.

a. ODM Use in the Western U.S.

The **California Subtropical Fruit, Truck, and Specialty Crop Region** comprises low mountains and broad valleys. It has a long, warm growing season and low precipitation. Very little precipitation falls from late April through October. A wide variety of crops are grown under irrigation**.**

ODM is used on Cole crops in the Central Valley and in Coastal Valleys of California.
It is used predominantly on broccoli and to a lesser extent on cauliflower and cabbage. This use represents approximately 30% of total ODM use in the U.S. The use of ODM on cotton in the Central Valley constitutes about 8% of total ODM use in the U.S. Use of ODM on alfalfa seed in the Central Valley represents about 4% of use in the U.S. (Gowan, 1997).

The **Sacramento and San Joaquin Valleys, commonly known as the Central Valley of California (MLRA 17)**, are predominantly farms and ranches (>90%). ODM is applied to cotton, cole crops, alfalfa seed, and other minor crops here. Slightly more than half the area is cropland which represents 60% of the cropland in California and 80% of the irrigated cropland in the state. Austin (1981) reports that 2-3% of the region is urban, and urbanization is increasing rapidly. Cotton, grain, fruits, nuts, grapes, rice, citrus and vegetables are grown on irrigated land. The more sloping non-irrigated cropland is dry-farmed to grain. About one-third of the region is in native grasses, brush and open woodland, and is used for grazing. The hazard of wind erosion is severe on the sandy, wind-modified soils in the San Joaquin Valley if plant cover is not maintained (Austin, 1981).

Elevations range from sea level to 200 meters. Average annual precipitation ranges from 125 to 625 mm (5" to 25"). Summers are long, hot, and dry, and winters are cool and rainy. Because of the low rainfall and relatively small streamflow, water is scarce in many parts of this area. Water for irrigated crops comes from stream diversions, wells, and canals (Austin, 1981).

The dominant soils are Xeralfs, Xerolls, Xererts, Aquents, Aquolls, Achrepts, Orthents, Fluvents, Psamments, and Argids (Austin, 1981). The soils are predominantly Hydrologic Group B, with some small areas of Hydrologic Group D (Kellogg, et al., 1992).

In the **Central California Coastal Valleys (MLRA 14)**, ODM is used on cole crops. Most of this region is farms and ranches. About 20% of the area is used for urban development which is increasing rapidly. This area is intensely farmed to many kinds of crops. Sites along streams are susceptible to flooding and bank cutting. Soils on hills are coarsely textured and the hazard of wind erosion is severe if the plant cover is removed (Austin, 1981).

Elevations range from sea level to 600 m, however, most of the area is less than 300 m. The average annual precipitation ranges from 300 to 750 mm (12" to 30"). This area is very dry from midspring to midautumn. The low to moderate rainfall and local streamflow are inadequate to meet present water needs. Water from adjoining areas is brought in for agriculture and domestic purposes. The yield of ground water in the deeper alluvial deposits, especially in Santa Clara Valley, is declining, and the intrusion of seawater is reducing the quality of water (Austin, 1981).

The dominant soils are Xeralfs, Xerolls, Xererts, Xerults, Aquents, Orthents, and Psamments (Austin, 1981). The soils in this area are a mixture of Hydrologic Group B, C, and D (Kellogg, et al., 1992).

The **Western Range and Irrigated Region** is a semi-desert to desert region of plateaus, plains, basins and isolated mountain ranges. The Western Range and Irrigated Region covers a large geographic region extending from central Oregon south to the Mexican border and west to Texas. The Yuma and Imperial Valleys are located in the southwest corner of this region.

The principle use of ODM in this region is on alfalfa grown for seed along the Snake River in Idaho and Oregon. There are many other minor uses in the Pacific Northwest region including mint, strawberries, sugar beets, and sweet corn.

Limited use of ODM occurs on cotton, melons, sweet corn, and sugar beets in the Imperial and Yuma Valleys of California and Arizona. (Gowan, 1997**).**

In the **Malheur High Plateau (MLRA 23)**, ODM is applied to alfalfa grown for seed and minor crops in Southern Oregon. Native vegetation covers much of this region. About 1 or 2 percent of this area is irrigated, and grain and hay for winter feed and pasture are grown. Average annual precipitation ranges from 200 to 350 mm (8" to 14") in most of the area, but as much as 500 mm (20") on some of the higher mountain slopes. Precipitation is fairly evenly distributed throughout fall, winter and spring, but is fairly low in summer. Water is scarce except in higher elevations where precipitation is greatest. Streamflow is erratic depending mostly on runoff from melting snow. The large ground water supplies in the gravel and sand filled valleys are largely untapped (Austin, 1981).

Most of the soils are Argids or Orthids. They are shallow to moderately deep, and have a medium textured to fine textured subsoil and a frigid or mesic soil temperature regime. Well drained Durargids and Durorthids have a duripan and are on lake terraces and fans (Austin, 1981). Most of the soils are Hydrologic Group D soils (Kellogg, et al., 1992).

In the **Northwestern Wheat and Range Region**, ODM is used on alfalfa grown for seed and minor crops in Idaho, Oregon, and Washington. Agricultural production in this region occurs in numerous MLRA's that cover much of central Washington and Oregon, part of eastern Washington, and areas along the Snake River in Idaho and Oregon. This region consists of smooth to deeply dissected plains and plateaus. The annual precipitation ranges from 250 to 575 mm (10" to 23") in most of the region (Austin, 1981).

Grazing is the major land use in the drier parts. Fruit is a major crop in the western part of the area. Grains, potatoes, sugar beets, and forage crops are grown under irrigation along the Snake River in the eastern part of the region. Xerolls, Borolls, and Ochrepts, derived mainly from loess, are the dominant soils in most of the region. Fluvents on flood plains are important for agriculture (Austin, 1981).

The **Yuma and Imperial Valleys** are collectively classified as **MLRA 31** and are named the Imperial Valley. ODM is used on cotton and other minor crops. Intensively irrigated agriculture is practiced in these areas and almost all water for agriculture comes from the Colorado River. Cotton, citrus, and vegetables are grown in this area. Non-irrigated land is in desert vegetation. Salinity of the soil is a major concern in this region. The average annual precipitation ranges from 50 to 100 mm (2" to 4"). Rainfall is too low to leach salts from the soils, so all leaching occurs with the use of irrigated water (Austin, 1981).

The dominant soils are Fluvents, Orthents, and Psamments. They are very deep and range from coarse to fine textured (Austin, 1981). The Imperial Valley had predominantly Hydrologic Group D soils; the Yuma Valley has Hydrologic Group A and B soils (Kellogg, et al., 1992).

b. Use of ODM in the Eastern U.S.

In the **Florida Subtropical Fruit, Truck Crop,and Range Region**, limited amounts of ODM are used on citrus crops (Gowan, 1997). The South Central Florida Ridge and the southern Florida Flatwoods regions are the principle citrus producing areas in Florida.

ODM is applied to citrus on the **South Central Florida Ridge**. This is the major citrus-producing area in Florida. Rainfall and ground water are abundant. The region is underlain by cavernous limestones. There are many lakes and sinkholes throughout the area but few perennial streams. The average annual precipitation ranges from 1275 to 1400 mm (51" to 56"). Maximum precipitation is in summer, and the minimum is in late autumn and in winter (Austin, 1981).

The dominant soils are Psamments and Udults. They range from excessively drained to very poorly drained. The excessive, and moderately drained soils are sandy throughout. The poorly drained soils often have thick sandy layers (Austin, 1981). The soils in this region belong predominantly to Hydrologic Group A (Kellogg, et al., 1992).

In the Southern Florida Flatwoods (MLRA 155), ODM is applied to some citrus fruits. The average annual precipitation ranges from 1300 to 1525 mm (52" to 61"). Maximum precipitation is in summer, and the minimum is in late autumn and in winter. Rainfall, surface water, and ground water supply an abundance of water. Ground water levels are controlled by canals and ditches.

The dominant soils are Aquods, Aquents, and Aquepts. They range from very poorly drained to moderately drained (Austin, 1981). The soils are predominantly Hydrologic Group B (Kellogg, et al., 1992).

For the **potential use of ODM on field corn**, this is currently limited to sweet corn and most of this use is in California. However, since the registration of ODM on field corn is being considered for reinstatement, this assessment will include the major corn production regions. The geographic distribution of field corn is primarily associated with the following major resource land areas (MRLAs): 1) Central Feed Grains and Livestock Region; 2) Atlantic and Gulf Coast Lowland Forest and Truck Crop Region; 3) Eastern section of the South Atlantic and Gulf Slope Cash Crop, Forest, and Livestock Region; 4) Northern Atlantic Slope Truck, Fruit, and Poultry Region; 5) Lake States Fruit, Truck, 6) Dairy Region; Western Great Plains and Irrigated Region; and 7) Northern Great Plains Spring Wheat Region (Austin, 1972). These regions are predominately representative of the climatic conditions of the eastern two-thirds of the United States. The precipitation gradient can range from 50 inches (125 cm) in the Northern Atlantic Slope Truck, Fruit, and Poultry Region to 20 inches (50 cm) in the western section of Western Great Plains and Irrigated Region. Although the distribution of precipitation varies among the corn growing regions, it is generally highest from late spring to midsummer.

Further analysis of the corn production area indicates some localized regions have a high pesticide vulnerability index for contamination of shallow ground water (Kellogg et al., 1992). These regions are the coastal plains of Georgia, S. Carolina, and N. Carolina; eastern section of Nebraska; the eastern shore region of Lake Ontario; and the Delmarva Peninsula. The most vulnerable soils for groundwater contamination appear to be associated with Psamment soils. The majority of the corn growing area is classified as Hydrologic Group B soils. Group B soils are characterized by moderately high to high saturated hydraulic conductivities (K_{sat}=0.36 to 3.60 cm/hr) and deep to very deep ground water. The major Group B soil subgroups are classified as Argiudolls, Hapludolls, Hapludalfs, and Dystrochepts. Small areas of concentrated Group C soils are found in Ohio, southern Iowa and Illinois, and Eastern Indiana. The major Group C soil subgroups are Hapludults and Hapludalfs. Also, the Gulf coast region of Texas consist of a high concentration of Group D soils. The major Group D soil subgroups are Ochraquults, Haplaquolls, Humaquepts, and Pelluderts. Group C and D soils are more prone to surface water runoff because of lower saturated hydraulic conductivities and/or relatively high water table.

2. Environmental Fate

a. Environmental fate assessment for Oxydemeton-methyl (ODM)

The environmental fate database for ODM is complete for the currently-registered uses of ODM. However, if the uses in the supplemental label are reinstated, EFED will require additional data on aerobic soil metabolism, aerobic aquatic metabolism (162-4) and soil mobility (163-1) for the persistent metabolites ODM-thiol and 2-(ethylsulfonyl) ethane sulfonic acid, since they do not appear to degrade in the environment and are considered to be mobile. These data on metabolites are needed to assess their potential to contaminate water resources and to estimate water concentrations using models. If the two persistent degradates do not show significant decline in the aerobic soil metabolism study, EFED will require field dissipation information on formation and decline of these two persistent degradates.

EFED has reviewed acceptable and supplemental data on parent ODM (S-[2-(ethylsulfinyl)ethyl]-O,O-dimethyl phosphorothioate) indicating that ODM degrades rapidly by microbially-mediated metabolism. This is supported by short half-lives in the aerobic soil metabolism and anaerobic aquatic metabolism studies (3.2 and 3.5 days, respectively). Parent ODM is consequently not expected to contaminate ground water and is not expected to persist or accumulate in surface water. Volatility is not a significant route of dissipation, based on the Henry's Law Constant of 1.5×10^{-11} Atm m^3 /Mol.

ODM quickly degrades to form two types of metabolites in the laboratory studies; non-persistent and persistent. The non-persistent metabolites include desmethyl ODM (S-[2-(ethylsulfinyl)ethyl]-O-methyl phosphorothioate), ODM-sulfide [MSI: (S-[2-(ethylthio)ethyl]O,O-dimethyl phosphorothioate)], ODM sulfone (S-[2-(ethylsulfonyl)ethyl] O,O-dimethylphosphorothioate), and desmethyl ODM sulfone (S-[2-(ethylsulfonyl)ethyl] O,O-methylphosphorothioate). These metabolites would not be expected to reach ground water due to their lack of persistence, and would not be expected to persist or accumulate in surface water. These metabolites are dephosphorylated and/or demethylated ODM.

The persistent metabolites formed in the laboratory studies submitted were ODM thiol (2-(ethylsulfinyl) ethane sulfonic acid), 2-(ethylsulfonyl) ethane sulfonic acid, and ESMSE (1-(ethylsulfinyl)-2-(methylsulfinyl)ethane). These metabolites are dephosphorylated and/or demethylated ODM. The metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid are formed under aerobic conditions, and appear to be persistent and mobile and may contaminate water resources. The ESMSE metabolite appears to be formed under anaerobic aquatic conditions only, and does not appear to degrade. It is not expected to be formed under most environmental conditions because ODM degrades very rapidly under aerobic conditions.

Under anaerobic aquatic conditions, parent ODM degraded rapidly to form ODM-sulfide (MSI) and EMSME. MSI in water increased from 0.1 % of applied at day zero to 53.9 % at 7 days, followed by a decline to non-detectable levels by six months. The other major metabolite, EMSME, reached a maximum of 17.6 % by 9 months, and was 12.9 % of applied by 12 months. MSI and EMSME were almost exclusively associated with water in the study. The calculated half-life for MSI in water was 9 days.

The only pH at which rapid degradation of parent ODM in sterile water was observed was pH 9, with a half-life of 2.5 days. Parent ODM hydrolyzed with extrapolated half-lives of 93 days at pH 5 and 40 days at pH 7. Photodegradation in water or on soil is not an important route of dissipation, with calculated half-lives of 137 days (194 days in pH 5 dark control pH buffer solutions) and 63 days (53 days in dark control soil). The only major photolytic transformation product was 2-(ethylsulfonyl) ethane sulfonic acid. This metabolite increased to a maximum concentration of 18.4 % of applied by the end of the study (30 days).

ODM is not persistent in aerobic soil and anaerobic aquatic environments. The aerobic soil metabolism half-life was 3.2 days in sandy loam soil. The major metabolites were ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid at maximum concentrations of 27-31 % of applied. Both of these metabolites are dephosphorylated and demethylated ODM and both kept increasing or reached constant concentrations in laboratory studies. The minor metabolite ODM sulfone did not exceed 6.3 % of applied by 3 days. Parent ODM also degraded rapidly ($t_{1/2}$=3.5 days) under anaerobic aquatic sediment/water conditions (Eh range of -65 to -2 mV for the 0-21 days used for half-life calculations). The major metabolites in the study were ODM sulfide and ESMSE. ODM sulfide was almost exclusively associated with water in the study, and degraded with a calculated half-life of 9 days. Non-extractable sediment residues increased to 25.5-26.7 % of applied by 2-3 months, and then declined to 18.3 % by 12 months.

Batch equilibrium data indicate that parent ODM partitions primarily in the liquid phase and is potentially very mobile in all tested soils. Parent ODM had Freundlich adsorption coefficients (K_d's) of 0.01 to 0.89 ml/g in sand, sandy loam, silt loam, and clay loam soils. No desorption coefficients could be calculated for parent ODM and no adsorption or desorption coefficients could be calculated for ODM sulfone and ODM sulfide due to limited adsorption. EFED has received no mobility information on the persistent metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid. Therefore, EFED is assuming that these persistent metabolites are at least as mobile as parent ODM.

Volatility of parent ODM and the organic metabolites is not expected to be a significant route of dissipation since no loss of material was observed in a laboratory volatility study. ODM has a vapor pressure of 2.85×10^{-5} Torr, a Henry's Law Constant of 1.5×10^{-11} Atm M^3 /Mol, and is miscible in water.

Based on supplemental data, ODM applied at 1 and 4.5 lbs ai/A rapidly dissipated ($t_{1/2}$'s=1.6 to 2.2 days) in field dissipation studies in California. The fields were irrigated and planted to sugar beets. The short half-lives are consistent with the aerobic soil metabolism half-life of 3.2 days. The short half-lives and the lack of observed leaching would indicate that aerobic soil degradation was the primary route of dissipation. Neither ODM nor ODM sulfone were detected after 14 days or below 6 inches of soil depth. No other metabolites were monitored in the study. ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid were the significant (>10 % of applied dose) metabolites in the aerobic soil metabolism study, and appear to be persistent and are considered to be mobile.

b. Environmental Fate Data Summaries

Hydrolysis (161-1)

In sterile, aqueous buffer solutions, radio labeled ODM, at 5 µg/ml, degraded with pH-dependent half-lives of 93 days at pH 5, 40 days at pH 7, and 2.5 days at pH 9. In pH 5 solutions, desmethyl ODM (S-[2-ethylsulfinyl)ethyl]-o-methylphosphorothioate) was the only observed metabolite, and continually increased to 24.5 % by 35 days. In pH 7 solutions, desmethyl ODM and another metabolite, ODM-Thiol, continually increased to 37.1 and 9.3 % of applied by 35 days, respectively. In pH 9 solutions, ODM-thiol increased to 75.3-79.5 % of applied by 15-22 days, and no desmethyl ODM was detected. The hydrolysis guideline requirement (161-1) is fulfilled (MRID 00143057).

Photodegradation in water (161-2)

Radio labeled ODM, at 0.67 µg/ml, degraded slowly in irradiated (29 days) and dark control sterile pH 5 buffer solutions with calculated half-lives of 137 and 194 days, respectively. The products formed were desmethyl ODM sulfone at sporadic concentrations of ≤7.4 % and ≤2.8 % of applied in irradiated and dark control solutions, ODM sulfone at ≤2.8 % of applied in dark control solutions (not-detected in irradiated solutions), and ODM-Thiol at ≤8.3 % of applied. The photodegradation in water guideline requirement (161-2) is fulfilled (MRID 40781501).

Photodegradation on soil (161-3)

MRID 40789701 was rejected on 8/23/89 since the proportion of metabolites formed was not presented in the study report. The registrant provided this information in a letter dated 2/11/92. The photodegradation on soil (161-3) guideline requirement is fulfilled (MRID 40789701).

Radiolabeled ODM, at 18.3 µg/g, had a degradation half-life of 63 days on sterile sandy loam soil that was irradiated with a xenon light source for 30 days. A similar half-life estimate (53 days) was observed in the dark control treatment on sterile soil. The major metabolite observed in the study was 2-ethylsulfonylethane sulfonic acid, which increased to 18.4 % by the end of the study (30 days of irradiation). Desmethyl ODM-sulfone did not exceed 2.8 % of applied in the study. Soil residues decreased with time. Unextractable residues did not exceed 6.1 % in the study samples. Volatile residues were not detected.

Aerobic soil metabolism (162-1)

Radiolabeled ODM, at 25 µg/g (10X rate), degraded with a calculated half-life of 3.2 days in a sandy loam (pH 7.5, 1.1 % OC). The major metabolites observed in the study were ODM-Thiol at a maximum of 31 % of applied at 3 months and 2-(ethylsulfonyl) ethane sulfonic acid at a maximum concentration of 27 % of applied at 12 months. These metabolites reached consistent levels of 19-30.5 % and 15.4-26.5 % of applied by 7-365 days. ODM sulfone did not exceed 6.3 % of applied. Radiolabeled bound residues (removable by HCl) did not exceed 9.1 % by one month after treatment and volatiles (primarily CO_2) did not exceed 9.3 % of applied by 12 months. The aerobic soil metabolism guideline requirement (162-1) is fulfilled (MRID 42830501) for the currently-registered uses. However, if the uses in the supplemental label are reinstated, EFED will require additional data on aerobic soil metabolism. These data will be used for the purpose of providing the modeling inputs to estimate concentrations in surface water and for use in the aquatic ecological risk assessment. If the two persistent degradates do not show significant decline in any future aerobic soil metabolism study, EFED will require field dissipation information on the formation and decline of these two degradates.

Anaerobic aquatic metabolism (162-3)

Radiolabeled ODM, at 2.5 µg/ml, degraded with a half-life of 3.5 days in a non-sterile, anaerobic aquatic sandy loam sediment:pond water system incubated at 25°C for up to 366 days. Levels of radiolabel extracted from soil never exceeded 3.4 % of applied, and non-extractable sediment residues reached a maximum of 25.5-26.7 % by 2-3 months, followed by a decline to 18.3 % by one year. Parent ODM degraded rapidly to form ODM-sulfide (MSI). MSI in water increased from 0.1 % of applied at day zero to 53.9 % at 7 days, followed by a decline to non-detectable levels by six months. The other major metabolite, ESMSE, reached a maximum of 17.6 % by 9 months, and was 12.9 % of applied by 12 months in water. MSI and EMSME were almost exclusively associated with water in the study. The calculated half-life for MSI in water was 9 days. The anaerobic aquatic metabolism guideline requirement (162-3) is fulfilled (MRID 42901801).

Aerobic aquatic metabolism (162-4)

No data on aerobic aquatic metabolism of ODM or its metabolites have been submitted.

There is uncertainty in the potential impact of ODM because there is insufficient environmental fate and phytotoxicity data for the metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid. These metabolites were formed at significant (>10 %) levels in the hydrolysis and aerobic soil metabolism studies, and did not appear to degrade. It is likely that these two metabolites will contaminate ground and surface water. These are the most likely metabolites to impact water quality, and the ecological impact is unknown. Therefore, if the uses in the supplemental labeling are reinstated, EFED will require additional data on aerobic aquatic metabolism using parent ODM and each of these metabolites in separate studies for the purpose of providing the modeling inputs to estimate concentrations in surface water and for use in the aquatic ecological risk assessment.

Soil adsorption/desorption (163-1)

These data were previously reviewed on 8/23/89 and rejected since the soil was sterilized with sodium azide, potentially changing the soil's chemical and physical properties. Sterilization was necessary since ODM is unstable in soil. The registrant referenced Wolf et al., 1989, who observed that the chemical properties of the tested soils (e.g. pH of soil/water matrix) were not significantly affected by sodium azide. Since the tested soils were not the same as in the literature article, EFED still has concerns about the sterilization method used for some of the soils. Physical or chemical sterilization of the soils (such as the use of sodium azide) may alter the soil's characteristics, complicating the interpretation of the results obtained. In this case, though, the Agency understands the need for soil sterilization since ODM degrades rapidly. The 163-1 data requirement is now satisfied for parent ODM, ODM sulfide (MSI), and ODM sulfone. However, the metabolites ODM-Thiol and 2-(ethylsulfonyl) ethane sulfonic acid were observed to form at significant ($\geq$10 % of applied) levels and did not appear to decline in other laboratory studies. Therefore, in the absence of data, EFED is assuming that these two metabolites are as mobile as parent ODM, and may contaminate water resources. The registrant may provide soil mobility information to refute or verify our assumption. Therefore, the adsorption/ desorption studies (163-1) only partially satisfy the data requirement at the present time (MRID's 40884201, 40884202).

The mobility and adsorption coefficients of parent ODM are shown in Table 1 (MRID 40884201). Because of low Freundlich K_{ads} values, calculation of desorption values for ODM was not possible. Poor goodness of fit (R^2) values were observed (0.22-0.39). Adsorption and desorption coefficients for the metabolites ODM sulfide (MSI) and ODM sulfone could not be determined since adsorption was <1 % (MRID 40884202).

Table 1. **Adsorption of Parent ODM in Soil (MRID 40884201).**

Soil (% OC)	Freundlich K_{ads} (ml/g)	1/n (Slope of Isotherm)
Sand (0.58 % OC)	0.09	0.89
Sandy Loam (0.64 % OC)	0.01	1.14
Silt Loam (1.69 % OC)	0.89	0.86
Clay Loam (1.28 % OC)	0.45	0.83

Laboratory Volatility (163-2)

Radio labeled ODM, at 5.2 ug/g soil did not volatilize from sandy loam soil. CO_2 was the only volatile compound trapped at 3.6 % of applied. The soil-extractable residues were identified as parent ODM at 12.4 %, ODM sulfone at 2.4 %, ODM-Thiol at 16.3 %, and thioethane sulfonic acid at 33.3 % of applied. The material balance was 92.4 % of applied at 192 hours. The stated vapor pressure was 2.8 x 10^{-5} mm Hg at 20 °C. The laboratory volatility guideline requirement (162-3) is fulfilled (MRID 40908801).

Terrestrial field dissipation (164-1)

This study was previously considered to be supplemental only since the laboratory data were previously considered to be not acceptable. EFED has since reviewed the aerobic soil metabolism study data (see above). The status of the 164-1 data requirement has, however, not changed. Only parent ODM and the non-persistent metabolite ODM sulfone were analyzed in the studies. The persistent metabolites ODM-thiol and 2-(ethylsulfonyl) ethane sulfonic acid were formed at significant levels in the aerobic soil metabolism study but were not monitored in the field dissipation study. These metabolites either reached constant levels or increased throughout the laboratory studies. If the two persistent degradates do not show significant decline in the required aerobic soil metabolism study (assuming reinstatement of uses in the supplemental label), EFED may require field dissipation information on the formation and decline of these two persistent degradates. This guideline is fulfilled for the current uses.

In the single application plot, parent ODM applied at 1.0 lb ai/A to sugar beets, rapidly dissipated ($t_{1/2}$=1.6-2.2 days) in sand and sandy loam soils at Chualar and Fresno, CA (pH 7.6-7.8, 0.44-0.84 % OC). Parent ODM was detected at 0.23-1.0 ppm on day zero, and then declined to non-detectable levels by 14 days. The metabolite ODM sulfone was not detected after 14 days. Neither ODM nor ODM-sulfone were detected below 6 inches of depth. In the multiple application plot, ODM was applied at 4.5 lbs ai/A to sugar beets. ODM and ODM sulfone were not detected after 7 days or below 6 inches of soil depth.

Bioaccumulation in Fish (165-4)

Bioaccumulation in fish was waived on 4/6/87 since the K_{ow} of ODM is low (0.18), indicating limited potential for accumulation.

C. Water Resources

ODM is not currently regulated under the Safe Drinking Water Act (SDWA). EPA's Office of Water has not established a Maximum Contaminant Level (MCL) or Health Advisory (HA) for ODM residues in drinking water (USEPA, 1996). The human health tolerance expression established for ODM includes ODM, and the metabolites ODM sulfone, desmethyl ODM sulfone, and desmethyl ODM.

(1) Surface Water

Parent ODM

Information from environmental fate studies indicates that parent ODM is not expected to persist and accumulate in surface waters, since ODM was not persistent to microbial-mediated metabolism. The reported half-lives for aerobic soil metabolism and anaerobic aquatic metabolism were 3.2 days and 3.5 days, respectively. Laboratory studies indicate that hydrolysis (at acid and neutral environmental pH's) and photodegradation would not cause rapid ODM degradation in the environment. The reported half-lives for acid hydrolysis, neutral hydrolysis, and photodegradation in water were 93 days, 40 days, and 137 days, respectively.

The reported vapor pressure (2.85×10^{-5} mm Hg), Henry's Law Constant of 1.5×10^{-11} Atm M^3 /Mol, and the solubility in water (miscible) indicate that ODM should not readily volatilize from surface water environments (EFED Fate One-Liner database). Based on the Freundlich adsorption coefficient (K_d's of 0.01-0.89, $K_{oc's}$ of 1.5-53) ODM is likely to be transported in surface runoff waters if rainfall occurs soon after application and runoff is generated. However, parent ODM is not predicted to persist in surface waters.

ODM Metabolites

ODM degrades to form two types of metabolites in the laboratory studies: non-persistent and persistent. The non-persistent metabolites include desmethyl ODM (S-[2-(ethylsulfinyl)ethyl]-O-methyl phosphorothioate), ODM-sulfide [MSI: (S-[2-(ethylthio)ethyl]O,O-dimethyl phosphorothioate)], ODM sulfone (S-[2-(ethylsulfonyl)ethyl] O,O-dimethylphosphorothioate), and desmethyl ODM sulfone (S-[2-(ethylsulfonyl)ethyl] O,O-methylphosphorothioate). These metabolites would not be expected to reach ground water due to their lack of persistence, and would not be expected to persist or accumulate in surface water. These metabolites are dephosphorylated and/or demethylated ODM.

The persistent metabolites formed in the submitted laboratory studies were ODM thiol (2-(ethylsulfinyl) ethane sulfonic acid), 2-(ethylsulfonyl) ethane sulfonic acid,], and ESMSE (1-(ethylsulfinyl)-2-(methylsulfinyl)ethane). These metabolites are dephosphorylated and/or demethylated ODM. The metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid are formed under aerobic conditions, and are persistent and considered to be mobile. Consequently, they are likely to reach water resources where they would persist and accumulate. The ESMSE metabolite formed under anaerobic aquatic conditions also did not appear to degrade. However, it is not expected to occur in the water column in significant amounts because ODM is likely to degrade rapidly in the field to other metabolites prior to runoff events.

Tier I Estimated Concentrations: Tier I EECs were not generated for ODM. EFED calculated Tier II EECs using PRZM-EXAMS.

Tier II Estimated Concentrations for Drinking Water and Ecological Exposure Assessment: Tier II estimated environmental concentrations (EECs) for ODM application to citrus in Florida, grain sorghum in Kansas, cotton and cabbage in California, alfalfa in Oregon, field corn in Iowa, and sweet corn in Georgia were calculated to generate aquatic exposure estimates for use in the ecological risk and human health risk assessments for parent ODM and its non-persistent metabolites. Cabbage was used as a surrogate for all desert vegetable crops. Since the non-persistent metabolites formed in the laboratory studies were not consistently observed between studies or were formed in only minor amounts, EFED used parent ODM as a surrogate for the non-persistent metabolites. The persistent metabolites were organosulfur compounds, not organophosphate compounds. Subsequently, these EECs are compared to ecotoxicity information for parent ODM in the risk assessment and characterization.

The Tier II EEC's generated in the RED were calculated using PRZM 2.3 for simulating the agricultural field and EXAMS 2.94 for fate and transport in surface water. EFED updated the EECs for the crops listed in the RED. These updated EECs are derived using the newer version of PRZM (PRZM 3.12) and EXAMS (2.975). EFED provided the updated and older EECs in an appendix for purposes of comparison.

For Florida citrus, EFED corrected the application rate and reran the scenario using the newer model to get updated EECs. The Florida citrus EECs were very different because an incorrect high application rate (1.88 lbs ai/A at 2 applications per year) was used previously, compared to the proper application rate (0.375 lb ai/A at 2 applications per year). All other scenarios that were run with the newer model provided similar concentrations as compared to the older EECs. Also, the desert scenarios do not take into account the required irrigation, which would increase the EECs. Table 3 below lists the PRZM 3.12 (updated) EECs.

To represent the uses, aerial or air blast applications were simulated, with 75% of each application landing on the field, 5% depositing in the pond, and the other 20% remaining airborne, or depositing off-site other than the pond. Table 1 in the appendix summarizes the maximum label rates and lists the emergence, maturity, and harvest dates for each crop and location modeled. Table 2 below outlines the environmental fate parameters used in the PRZM-EXAMS modeling.

Table 2. ODM Environmental Fate Parameters used in PRZM-EXAMS Modeling.

Parameter	Value	Source	Uncertainty Factor[1]	PRZM-EXAMS Value	Rate Constants (K-value)
Freundlich K_{ads} (ml/g)	0.45 ml/g	MRID 40884201	Not applicable	0.45 ml/g	Not applicable
Aerobic Soil Metabolism $T_{1/2}$ (days)	3.2 days	MRID 42830501	3	9.6 days	0.072 day^{-1}
Aerobic Aquatic Metabolism $T_{1/2}$ (days)	Stable (no available data)	None	Not applicable since there was no data.	No available data	0.0 day^{-1}

Anaerobic Aquatic Metabolism $T_{1/2}$ (days)	3.5 days	MRID 42901801	3	10.5 days	0.066 day^{-1}
Water solubility (mg/L)	Miscible	EFGWB One-liner Database	Not applicable	1,000 mg/L	Not applicable
Hydrolysis (pH 7)	40 days	MRID 00143057	Not applicable	40 days	$4.6e^{-4}$ $hours^{-1}$ (Hydhaf program)
Hydrolysis (pH 9)	2.5 days	MRID 00143057	Not applicable	2.5 days	$1.11e^{+3}$ $hours^{-1}$ (Hydhaf program)
Aqueous Photolysis (days)	137 days	MRID 40781501	Not applicable	137 days	2.1 x 10^{-4} $hour^{-1}$

[1] When only one metabolism half-life is available, the half-life is multiplied by 3 for surface water modeling purposes, according to EFED policy.

The hydrolysis half-lives from the acceptable hydrolysis study were used as inputs into the HYDHAF program, which calculates hourly rate constants for EXAMS. The aqueous photolysis half-life was modified by the formula Ln 2/($T_{1/2}$ x 24) to convert the 137 day half-life to hours in EXAMS. The metabolism half-lives were multiplied by a factor of 3 to account for the uncertainty of having only one half-life for each guideline. The half-lives for metabolism were converted to daily rate constants for PRZM using the formula Ln 2/(3 x $T_{1/2}$). For EXAMS, the metabolism rate constants were calculated on a daily basis using the above formula, and then divided by 24. Water solubility of 1,000 mg/kg was used as an upper bound. The Freundlich K_{ads} value of 0.45 was the lowest non-sand adsorption coefficient, and was used because adsorption of ODM does not appear to be related to soil organic carbon content.

A Tier II EEC uses a single site which represents a high exposure scenario for the use of the pesticide on a particular crop or non-crop use site. The weather and agricultural practices are simulated at the site over multiple (in all cases, 36) years so that the probability of an EEC occurring at that site can be estimated.

The scenarios chosen represent sites that are representative of the current and expected areas of ODM use. However, it is recognized that for the desert scenarios, many crops are grown year-round, and there is a complex crop rotation scheme every year. The simulations were performed using maximum application rates ranging from 0.75-2.25 lbs ai/A and with the maximum number of three yearly applications. The intervals between applications ranged from 7-14 days, based on the need to control sucking insects (See Table 1 in Appendix). The EECs were calculated so that an exceedance for the maximum average concentration of that duration in that year at that site is expected to happen every 10 years. With the exception of the Pico sandy loam soil (Group B), all soils were either Group C or D soils, which are more prone to runoff than leaching. The Adamsville sand in Osceola County, FL, is classified as a hyperthermic, uncoated, Aquic Quartzpsamment. This soil has hydrologic groupings that range from A to C (Caldwell and Johnson, 1981). The wide hydrologic groupings indicate that the Adamsville sand is characterized by highly divergent soil properties, coarse textured surface soils coupled with a seasonally high water table. The depth of the water table is expected to control the Hydrologic Soil Grouping classification. A high water table in the soil profile should promote a moderately high runoff potential. In the PRZM-EXAMS modeling, the Adamsville sand was considered as a Hydrologic Group C Soil by using appropriate curve numbers. At present, EFED's models do not consider the potential soil hydrologic interactions between ground and surface water. The Tier II upper tenth percentile EECs are listed in table 3.

Table 3. Updated Tier II upper tenth percentile EECs for ODM for simulated crops.

Crop	Maximum ($\mu g \cdot L^{-1}$)	4 Day ($\mu g \cdot L^{-1}$)	21 Day ($\mu g \cdot L^{-1}$)	60 Day ($\mu g \cdot L^{-1}$)	90 Day ($\mu g \cdot L^{-1}$)	Long-term Mean* ($\mu g \cdot L^{-1}$)
Alfalfa for seed (Oregon, PRZM 3.12)	2.1	1.9	1.3	0.8	0.6	0.2
Cabbage (Imperial Valley, CA, PRZM 3.12)	3.4	3.2	2.6	1.6	1.1	0.5
Cabbage (Coastal Valley, CA, PRZM 3.12)	3.6	3.4	2.9	2.2	1.7	0.5
Citrus (Florida, PRZM 3.12, 0.375 lb ai/A *2 apps)	7.0	6.4	4.6	2.5	1.8	0.5
Cotton (Imperial Valley, CA, PRZM 3.12)	3.1	2.8	1.9	1.3	0.9	0.2

Grain Sorghum (Kansas, PRZM 3.12)	10.9	9.7	6.8	3.7	2.7	0.7
Sweet Corn (Georgia, PRZM 3.12)	12.4	11.5	8.3	4.8	3.4	0.9
Field Corn (Ohio, PRZM 3.12)	6.5	5.9	4.6	2.6	1.8	0.5
* Upper 90% confidence bound on the 36 year mean with the variance calculated from the annual means.						

Annual climatic data from 1948 to 1983 were obtained for the Major Land Resource Areas and listed in Table 1 appended to this document. Thirty-six consecutive PRZM-EXAM simulations were conducted to evaluate the cumulative probability distribution for peak, 4-day, 21 day, 60 day, and 90 day EECs. The one-in-10 year PRZM-EXAMS Peak EECs for parent ODM and the non-persistent metabolites ranged from 2.1-12.4 $\mu g \cdot L^{-1}$ (Table 3). Accumulation in water bodies is not expected, as shown in Figures 1-8 (appendix). In all the modeled crops, approximately 53-75 % of estimated ODM residues declined in the pond by 90 days. In the simulations that involved desert or dry areas (cotton, cabbage, and alfalfa grown for seed), the decline curves were virtually identical from year-to-year in the 36-year modeled period because the weather inputs did not vary significantly from year to year. Consequently, mean concentrations did not vary. The model simulations use weather as an input, and did not take into account irrigation. The other modeled uses (field corn, grain sorghum, sweet corn, and citrus) demonstrated variability in the decline curves from year-to-year in the 36-year modeled period that appeared to be a result of differences in the weather inputs between years. Virtually all pond residues were associated with the aqueous phase. Aerobic aquatic metabolism data were not available for input into the model, and therefore ODM was assumed to be stable to metabolism in aerobic water:sediment systems. However, EFED notes that aerobic soil and anaerobic aquatic metabolism laboratory studies indicate that ODM is not persistent.

Several ODM residues in the human health tolerance expression (ODM, ODM sulfone, desmethyl ODM, and desmethyl ODM sulfone) do not appear to be persistent and were not formed in significant quantities ($\geq$10 % of applied) in the laboratory studies. Therefore, the use of parent ODM as a surrogate for the non-persistent metabolites is reasonable. However, there is some uncertainty in the potential impact to water quality from the metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid because of insufficient environmental fate and transport data. These metabolites were formed at significant (>10 %) levels in the hydrolysis and aerobic soil metabolism studies, and did not appear to degrade. A more complete environmental fate assessment for these two metabolites will ~~probably~~ require additional aerobic soil metabolism, aerobic aquatic metabolism and soil mobility data. The data will provide the inputs necessary to calculate EEC's using PRZM-EXAMS.

There are certain limitations imposed when Tier II EEC's are used for drinking water exposure estimates. Obviously, a single 10 hectare field with a 1 hectare pond does not accurately reflect the dynamics in a watershed large enough to support a drinking water facility. A basin of this size would certainly not be planted completely to a single crop nor be completely treated with a pesticide. Additionally, treatment with the pesticide would likely occur over several days or weeks, rather than all on a single day. This would reduce the magnitude of the concentration peaks, but also make them broader, reducing the acute exposure but perhaps increasing the chronic exposure. The fact that the simulated pond has no outlet is also a limitation as water bodies in this size range would have at least some flow through (rivers) or turnover (reservoirs). Also, irrigation of crops in the desert scenarios was not considered in the models. EEC's would likely be higher if EFED had irrigation data available. In spite of these limitations, a Tier II EEC can provide a reasonable upper bound estimate of the concentration found in drinking water if not an accurate assessment of the real concentration. Risk assessment using Tier II values can be used as refined screens to demonstrate that the risk is below the level of concern.

Surface Water Monitoring Data

Limited water resource monitoring data for ODM are available. Data from the STORET database were reported during 1984-1997 from wells and surface water in California (2 samples) and in New Mexico (94 samples). All samples were either below detection limits or between the detection limit and quantitation limit, with a detection limit of 0.090-0.5 ppb (90-500 ppt). It was not possible to ascertain whether the samples were all from agricultural areas where ODM is used.

There are no USGS NAWQA data available for ODM residues in surface water. A search of the California Department of Pesticide Regulation surface water database found no additional information for ODM in California. These records represent approximately 100,000 surface water samples taken throughout the State (California, 1997). Because of the lack of adequate surface water monitoring data, modeling results are recommended for the purpose of risk assessment.

2) Ground water

Parent ODM and the metabolites ODM sulfone, desmethyl ODM sulfone, and desmethyl ODM are believed to be mobile but not persistent. These metabolites will be referred to as the "non-persistent" metabolites of ODM. Based on their environmental fate characteristics and supporting ground water modeling, both ODM and the non-persistent metabolites are not expected to leach to ground water. **Estimated maximum concentrations in ground water to be used for exposure and risk assessment purposes are 0.006 µg ·L**$^{-1}$.

The metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid are believed to be mobile and persistent and as a result they have the potential to leach to ground water. They may or may not be current human health concerns in drinking water. However, since these are the most likely metabolites to impact water quality, and the ecological impact is unknown, additional environmental fate data will be requested as part of the reregistration process if the uses on the supplemental label are reinstated.

The environmental fate information for the ODM metabolites is extremely limited. No adsorption or desorption coefficients could be calculated for the metabolites ODM sulfone or MSI because of limited adsorption. In the field dissipation study neither ODM or ODM sulfone were detected after 14 days or below 6 inches of soil depth.

Ground Water Monitoring Data

EPA's "Pesticides in Ground Water Database" records that two wells in Merced County California were sampled for ODM between 1984 and 1985. No residues of ODM were detected in the samples with a detection limit of 5 ppb for the analysis (California, ND). The California Department of Pesticide Regulation reported that 28 wells in 11 counties were sampled for ODM between April and May, 1996. No residues of ODM were detected in the samples, the detection limit was 0.1 ppb (California, 1997). No monitoring data are currently available from the U.S.G.S. for ODM in ground water. Since the ground water monitoring data for ODM are limited, ground water screening models were used to estimate the potential leaching of ODM and its non-persistent metabolites.

In the RED, EFED used the PATRIOT model for estimating concentrations in ground water for the drinking water assessment. EFED is not currently using the results of the PATRIOT model for ODM because we have no official Tier II ground water model.. Also, PATRIOT modeling was conducted using an incorrect application rate as a model input for citrus. The modeling assumed two applications of 1.88 lbs ai/A for a total application rate of 3.76 lbs ai/A/yr. The correct application rate is 0.375 lb ai/A at 2 applications per year for a total of 0.75 lb ai/A/yr. Instead of the PATRIOT modeling, EFED is currently using the results of the SCI-GROW model for drinking water assessment. Therefore, the PATRIOT modeling details for ODM are included in the appendix.

Estimated Concentrations in Ground Water

The SCI-GROW model (Screening Concentrations in Ground Water) is a model for estimating concentrations of pesticides in ground water under "maximum-loading" conditions. SCI-GROW provides a screening concentration; an estimate of likely ground water concentrations if the pesticide is used at the maximum allowed label rate in areas with ground water exceptionally vulnerable to contamination. In most cases, a majority of the use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate (Barrett, 1997).

The SCI-GROW model is based on scaled ground water concentrations from ground water monitoring studies, environmental fate properties (aerobic soil half-lives and organic carbon partitioning coefficients-Koc's) and application rates.

Results from the SCI-GROW screening model predict that the maximum chronic concentration of ODM and its non-persistent metabolites in shallow ground water is not expected to exceed 0.006 µg $\cdot L^{-1}$ for the majority of the use sites. A 2.25 lbs ai/A/yr application to cabbage to citrus was modeled. Other model inputs include a 3.2 day half-aerobic soil half-life and a K_{oc} of 122 ml/g. Estimated concentrations in ground water will be proportionally lower in relation to the amount applied.

Model Assumptions and Uncertainties:

EFED's evaluation includes crops that could be reinstated for use. Maximum application rates were calculated and used for all modeling. The maximum number of allowed applications per season were also used. Each of the modeled scenarios (except citrus in Florida) used three applications per season. The citrus application rate (2 applications of 1.88 lbs ai/A) used in the PATRIOT modeling was incorrect. Therefore, EFED is not currently using the results of this analysis. The citrus label only allows up to two applications per year of 0.375 lb ai/A for a total of 0.75 lb ai/A/yr.

PATRIOT was used as a screening model to evaluate the potential of ODM to reach very shallow ground water. It is believed that PATRIOT assumes 100% application to the soil with no losses due to foliar uptake or to spray drift. The depth to ground water for the soils used in the modeling ranged from 3 to 6 feet in depth. These depths may not always be representative of the depth to ground water in the ODM use areas.

Cropping data for California and Oregon was incomplete in the PATRIOT database model, so crop data from the PRZM-EXAMS surface water modeling was used. Complete soil information was also not available for all areas of California. The use of surrogate soil information for California increased the uncertainty of the evaluation. To compensate for this, four different major agricultural soils were modeled for the Central Valley of California to represent ODM use on cotton, alfalfa for seed, and cole crops. Site specific corrections were made for general irrigation and evaporation and included in the modeling. Refer to an appendix for more detailed information.

These PATRIOT modeling results are an over estimation of the mass of pesticide available to potentially leach to ground water, as a result of the extremely shallow depth to ground water used in this modeling.

The SCI-GROW model is based on small-scale ground water monitoring studies conducted on highly vulnerable sandy soils with shallow ground water (10-30 ft in depth). Uncertainties in the SCI-GROW model are: 1) The model does not consider site specific factors regarding hydrology, soil properties, climatic conditions, and agronomic practices, 2) The model does not account for volatilization, and 3) Predicted ground water concentrations are linearly extrapolated from the application rates. This model is based on actual field data from "worst case" ground water monitoring studies conducted on sandy soils and with heavy irrigation. Therefore, the results should be considered to be a "worst case" or "upper bound" for ODM and its non-persistent residues in ground water.

3. Ecological Toxicity Data

a. Toxicity to Terrestrial Animals

i. Birds, Acute and Subacute

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of ODM to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated below.

The avian toxicity tests available are for formulated product with 50% active ingredient. For purposes of the risk assessment, the Agency has estimated toxicity of the technical grade from tests with formulated product.

Avian Acute Oral Toxicity

Species	LD50 (mg ai/kg)[2]	Toxicity Category	Study Classification[1]
Northern bobwhite quail *(Colinus virginianus)*	17	Highly toxic	Core for a formulated product.
Mallard duck *(Anas platyrhynchos)*	27	Highly toxic	Supplemental
Japanese quail	42	Highly toxic	Supplemental
California quail	24	Highly toxic	Supplemental
Pheasant	21	Highly toxic	Supplemental
Chukar	60	Moderately toxic	Supplemental
Rock Dove	7	Very Highly toxic	Supplemental
House sparrow	35	Highly toxic	Supplemental

[1] Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)
[2] Converted from an LC50 based on testing with 50% a.i. to an estimated LC50 for 100% a.i.

ODM is generally highly toxic to avian species on an acute oral basis. Each individual study by Hudson et al. does not fulfill the guideline requirement because there were too few birds per test level. However, collectively, these studies satisfy the requirement. The guideline (71-1) is fulfilled (MRID 00060636 & 00160000).

Two subacute dietary studies using the TGAI are required to establish the toxicity of ODM to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Avian Subacute Dietary Toxicity

Species	5-Day LC50 (ppm)[1,2]	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	217	Highly toxic	00022923 Hill et.al./1975	Core
Mallard duck *(Anas platyrhynchos)*	>2500	Slightly toxic to practically nontoxic	00022923 Hill et.al./1975	Core

[1] Test organisms observed an additional three days while on untreated feed.
[2] Converted from an LC50 based on testing with 50% a.i. to an estimated LC50 for 100% a.i.

ODM is highly to practically nontoxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID 00022923).

ii. Birds, Chronic

Avian reproduction studies using the TGAI are required for ODM because birds may be subject to repeated exposure to the pesticide, especially preceding or during the breeding season. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

Avian Reproduction

Species	% ai	NOAEC (ppm)	LOAEC (ppm	Basis (Endpoints affected)	MRID No. Author/Year	Study Classification
Northern bobwhite quail *(Colinus virginianus)*	92.4	1.8	6.9	Primarily based on reduced 14 day survivor weight (see text)	40747202 Beavers et.al./1988	Core
Mallard duck *(Anas platyrhynchos)*	92.4	17.3	54.0	Based on reduced food consumption	40747201 Beavers et.al./1988	Core

In the bobwhite quail study, endpoints with statistically significant effects were as follows:

- Doses   6.9 ppm resulted in statistically significant reduction of weight of the offspring surviving 14 days. There were also statistically significant differences in the mean for eggs laid/hen and for eggs set/hen at 6.9 ppm and higher, but for those endpoints the effect at 6.9 was to somewhat increase the number of eggs relative to controls. (Note that eggs laid/hen and set/hen are correlated so similar results are anticipated for the two endpoints.)
- At 17.3 ppm effects were present for additional endpoints, number of viable embryos and live three week embryos per hen.

In the mallard duck study, statistically significant differences were noted at the 17.3 ppm treatment level for reduced food consumption. There were no treatment related effect upon reproduction in this study. Based on these results EFED finds that the avian chronic NOAEC (the highest dose tested without observing an adverse effect) is 1.8 ppm. The guideline (71-4) is fulfilled (MRID 40747202 & 40747201).

The primary basis for the avian chronic NOAEC for ODM is the results for 14 day old survivor weights in the study (MRID 40747202) with bobwhite quail. For that endpoint, the results of the study are displayed below:

Results from the ODM bobwhite chronic toxicity study for weight of 14-day survivors.

	Control	**Measured Concentration (Nominal concentration)**		
		1.8 ppm (3 ppm)	**6.9 ppm (10 ppm)**	**17.3 ppm (30 ppm)**
Mean weight	***C*** = 26.2	***T*** = 25.7	23.2	23.7
%Change in mean =100(*C*-*T*)/*C*	--	2% decrease	11% decrease*	10% decrease*
num. chicks	13	14	9	14

* Statistically significant decrease in mean relative to control based on both Bonferroni t-tests (for 3 comparisons) and Williams test. Tests were one-sided tests for a decrease. Assumptions of parametric tests were tested and not rejected. Error SS =302. (ToxStat results.)

iii. Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported below.

Mammalian Toxicity

Species	% ai	Test Type	Toxicity Value	Affected Endpoints	MRID No.
laboratory rat (*Rattus norvegicus*)	93.3	Acute oral	Female LD_{50} = 48 mg/kg (960 ppm) Male LD_{50} = 61 mg/kg (1220 ppm)	Death	40779801

Death occurred on day 0 in all males that died and day 0 to day 5 in females. Death occurred more frequently at day 0 at 80 to 100 mg/kg and more frequently later at lower dose levels in females. Clinical signs of toxicity appeared the day of dosing (day 0), such as muscle fasciculation, tremor, urine stain, decreased motor activity, yellow anal stain, salivation, lacrimation and convulsions, but were resolved by day 9 in surviving animals. Gross lesions occurring in animals that died were unilateral ocular opacity and gas filled intestines; however, these lesions were not seen in surviving animals at day 14. There appeared to be dose related decreased body weight among surviving animals, starting at 20 mg/kg.

This acute oral study is classified as acceptable. This study satisfies the HED guideline requirement for an acute oral study (81-1) in the rat (MRID 40779801).

In a 2-generation study of reproduction (MRID 41461901), test material (50% ai) was administered to 35 Sprague Dawley rats throughout 2 generations. The parental NOEL = 4.5 ppm and LOAEL = 25 ppm (both adjusted for purity of the test material) were based on decreases in male fertility and female fertility of unknown origin in the P and F_1 generations. Other effects, epididymal vacuolation, body weight reduction, testes weight reduction, ovarian weight reduction, and nominally increased estrous cycle length in females, were also noted at various concentration levels. Adult cholinesterase inhibition NOEL < 0.5 ppm and LOAEL = 0.5 ppm (both adjusted for purity of the test material) was based on brain cholinesterase inhibition.

This study is classified as acceptable. This study satisfies the HED guideline requirement (83-4) for effects on reproduction in the rat (MRID 41461901).

Oxydemeton-methyl (ODM) as the 92.5% technical grade was administered in the feed (corn oil vehicle) to 40 male Sprague Dawley rats per group at 0 or 50 ppm (1.9 mg/kg/day) for 10 weeks (MRID# 424990101 & 42500101). Females (30 per group) were untreated. Ten dosed males were killed for necropsy and cholinesterase determination at week 10.

No effects were noted on male fertility or any other reproductive parameter determined in the mated females. Histological examination indicated that compound related effects occurred only in the epididymides. The epididymides of the 50 ppm dose group were vacuolated in the proximal corpus of the epididymis. However, the absolute testes weight, but not the relative testes weight, was statistically significantly decreased in the 50 ppm dose group.
Cholinesterase was inhibited in the plasma (59%), erythrocytes (100%) and brain (77%) of males in the 50 ppm dose group.

Male body weights were statistically significantly decreased after 100-101 days on study, but not after 70 days. In other studies at 50 ppm marginal body weight decrement to no decrement occurred at 195 days after initiation of the study.

In a previous two-generation study on reproduction, fertility effects, litter and pup effects were noted at 50 ppm. This study demonstrates that fertility effects noted in the two-generation study were due to effects on the female and not on the male. It also demonstrates that the epididymal vacuolation occurring in both studies probably had no effect on fertility. It should be pointed out, that fertility in males rats can be reduced to 20% of normal before effects are noted on fertility. In addition, effects on male fertility and sperm motility were demonstrated in a 5 day dosing study at 5 mg/kg/day.

This study is acceptable for a special HED study on male fertility (MRID# 424990101 & 42500101).

Based on the above results, the NOEL of 9 ppm will be used in the ecological risk assessment.

iv. Insects

A honey bee acute contact study using the TGAI is required for ODM because its use will result in honey bee exposure. Results of this test are tabulated below.

Nontarget Insect Acute Contact Toxicity

Species	% ai	LD50 (g/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee *(Apis mellifera)*	Technical	3.0	Moderately toxic	00036935 Atkins et. al./1975	Core
Honey bee *(Apis mellifera)*	Technical	0.54 (contact) 0.31 (oral)	Highly toxic	05001991 Stevenson/1978	Core

The results indicate that ODM is moderately to highly toxic to bees on an acute contact and oral basis. The guideline (154-24) is fulfilled (MRID 00036935 & 05001991).

A bee toxicity study (MRID 00060628), to determine the toxicity of residual ODM on foliage to honey bees, provided the following information: ODM was found to have short-lived toxicity to honey bees and alkali bees exposed to foliar residues. At 0.5 lb ai/A, 3-hr old residues were low in toxicity to both species (2-20% mortality, evaluated at 24 hours). This study fulfills the guideline requirement for testing residual toxicity to honey bees.

A study (MRID 00074486) on the effects of pesticides on apiculture revealed supplemental information. When honey bee larvae were exposed to oxydemeton-methyl, the 3-4 day old larvae were the most susceptible age group (LD_{50} = 2.15 µg/larva), while 5-6 day old larvae were the least susceptible (LD_{50} = 24.39 µg/larva). These figures compare to an adult LD_{50} of 3 ug/bee. This study provides some useful information (supplemental) but does not fulfill any guideline requirement.

A lab residual fumigant toxicity study (ID 05002083) did not show any initial or residual fumigant toxicity to the honey bee from ODM. This study provides supplemental information, but does not fulfill any guideline requirement.

v. Terrestrial Field Testing

A simulated field study with English sparrows, bobwhite quail, and New Zealand rabbits was performed in 1973 (MRID 00060638) and was found to provide supplemental information. The animals were exposed to both treated and untreated alfalfa at an application rate of 2.25 lb ai/A, applied 3 times with a two week application interval. The caged animals were placed on alfalfa plots for 6 weeks; they were moved to fresh alfalfa plots weekly which had received previous applications.

There was no treatment-related mortality of quail during the 42 day study. Weight losses for both treated and control birds were equivalent.

The treated rabbits had no toxic symptoms or deaths, although one control rabbit died.

There were high mortalities of control and treated sparrows, particularly during the last week of the study. The high death rate was attributed to stress due to being caged over an extended period of time.

The data indicate that a formulated product of ODM, metasystox-r, was not significantly hazardous to caged bobwhite quail, English sparrows, and New Zealand rabbits. However, issues such as repellency were not considered. Without knowing the sizes of the cages, it is difficult to know if the animals were adequately exposed to treated food. This study provides some useful information, but does not fulfill any guideline requirement.

b. Toxicity to Freshwater Aquatic Animals

i. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of ODM to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

Freshwater Fish Acute Toxicity (Technical)

Species	% ai	96-hour LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	97.9	0.73	Highly toxic	STOOXY01 US EPA/1978	Core
Bluegill sunfish *(Lepomis macrochirus*	97.9	1.22	Moderately toxic	STOOXY02 US EPA/1978	Core

Technical ODM ranges from moderately to highly toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID STOOXY01, STOOXY02).

Freshwater fish toxicity studies on the formulated product were also submitted for ODM. Results of these tests are tabulated below.

Freshwater Fish Acute Toxicity (Formulated product)

Species	% ai	96-hour LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	25	23	Slightly toxic	00074349 Nelson et.al./1977	Core for formulated product
Rainbow trout *(Oncorhynchus mykiss)*	50	6.4	Moderately toxic	00003503 Johnson & Finley,/1980	Core for a formulated product
Bluegill sunfish *(Lepomis macrochirus)*	50	13.0	Slightly toxic	00003503 Johnson & Finley,/1980	Core for a formulated product
Bluegill sunfish *(Lepomis macrochirus)*	50	1.9	Moderately toxic	00060639 Lamb & Roney/1973	Core for a formulated product
Bluegill sunfish *(Lepomis macrochirus*	25	26	Slightly toxic	00074349 Nelson et.al./1977	Core for formulated product

The formulated product of ODM is moderately to slightly toxic on an acute basis.

ii. Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for ODM because the end-use product is expected to be transported to water from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, and (2) any aquatic acute LC50 or EC50 is less than 1 mg/l (rainbow trout LC_{50} = 0.73 mg/L). The preferred test species is rainbow trout. Results of this test are tabulated below.

Freshwater Fish Early Life-Stage Toxicity Under Flow-through Conditions

Species	% ai	NOAEC (ppm)	LOAEC (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Rainbow trout *(Oncorhynchus mykiss)*	97.7	2.6	4.9	Fry survival and growth.	41054501 Cohle/1989	Core

[1] defined as the geometric mean of the NOAEC and LOAEC.

This study showed effects on fry survival and growth at 4.9 ppm. This data may not be reliable (based on the acute LC_{50} being lower than the chronic NOAEC), but, because the environmental exposure is not expected to be of concern, no new data is requested at this time. The guideline (72-4) is fulfilled (MRID 41054501).

iii. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of ODM to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Freshwater Invertebrate Acute Toxicity (Technical)

Species	% ai	48-hour LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	94.6	0.24	Highly toxic	40286801 Forbis/1987	Core
Scud (*Gammarus fasciatus*)	Technical	1.0 (reconstituted H_2O) and 1.1 (well H_2O)	Moderately to highly toxic	05017538 Sanders/1972	Supplemental
Scud (*Gammarus fasciatus*)	Technical	0.19	Highly toxic	00097842 Sanders/1969	Supplemental

ODM is highly to very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID 40286801).

Freshwater invertebrate toxicity studies on the formulated product were also submitted for ODM. Results of these tests are tabulated below.

Freshwater Invertebrate Acute Toxicity (Formulated product)

Species	% ai	48-hour LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	50	0.16 (nominal)	Very highly toxic	00158213 Heinbeck/1985	Supplemental
Waterflea *(Daphnia magna)*	50	0.0033	Very highly toxic	00074350 Nelson et.al./1977	Supplemental

The formulated product of ODM is very highly toxic to aquatic invertebrates.

iv. Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for ODM since the end-use product is expected to be transported to water from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, and (2) any aquatic acute LC50 or EC50 is less than 1 mg/l (rainbow trout LC_{50} = 0.73 mg/L and daphnia EC_{50} = 0.23 mg/L). The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Freshwater Aquatic Invertebrate Life-Cycle Toxicity

Species/Static Renewal or Flow-through)	% ai	21-day NOAEC (ppm)	Endpoints Affected	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	97.7	0.046	adult mean length, survival, and young/adult/day	40986601 Burgess/1991	Core

The guideline (72-4) is fulfilled (MRID 40986601).

c. Toxicity to Estuarine and Marine Animals

i. Estuarine and Marine Fish, Acute

Acute toxicity testing with estuarine/marine fish using the TGAI is required for ODM because the end-use product is expected to reach the marine/estuarine environment (it is used in coastal counties; i.e., FL and CA). The preferred test species is sheepshead minnow. Currently, EFED has no estuarine/marine fish data. The guideline requirement (72-3a) is not fulfilled.

ii. Estuarine and Marine Fish, Chronic

These data are in reserve pending the results of the acute testing with the TGAI.

iii. Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for ODM because the end-use product is expected to reach the marine/estuarine environment (it is used in coastal counties). The preferred test species are mysid and eastern oyster. Currently, EFED does not have data on the TGAI. The guideline requirements (72-3 b & c) are not fulfilled.

Acute toxicity testing with estuarine/marine invertebrates using a formulated product for ODM were submitted for ODM. The results of these tests are tabulated below.

Estuarine/Marine Invertebrate Acute Toxicity (Formulated product)

Species	% ai.	96-hour EC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Pink shrimp (*Penaeus duorarum*)	25	1.2	Moderately toxic	00074348 Heitmuller/1975	Core for a formulated product
Fiddler crab	25	8.6	Moderately toxic	00074348 Heitmuller/1975	Core for a formulated product

The formulated product of ODM is moderately toxic to estuarine/marine shrimp and fiddler crabs on an acute basis.

iv. Estuarine and Marine Invertebrate, Chronic

These data are in reserve pending the results of the acute testing.

d. Toxicity to Plants

i. Terrestrial Plants

Currently, terrestrial plant testing is not required for pesticides other than herbicides except on a case-by-case basis. Terrestrial plant testing is not required for ODM; the criteria, outlined in 40 CFR part 158.540 are not met.

ii. Aquatic Plants

Currently, aquatic plant testing is not required for pesticides other than herbicides and fungicides except on a case-by-case basis. Aquatic plant testing is not required for ODM; the criteria, outlined in 40 CFR part 158.540 are not met.